

### **REMARKS**

Reconsideration of the allowability of the present application is requested respectfully.

### **Status of the Claims**

Claims 2 to 11, 21 to 28, and 30 to 34 were acted upon by the Examiner. Claim 34 has been cancelled. Claims 21, 30 and 31 have been amended. No claims have been added. Accordingly, Claims 2 to 11, 21 to 28, and 30 to 33 are presented for examination.

### **ARGUMENTS**

#### **The 35 U.S.C. §112, second paragraph, Rejections**

Claim 30 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner asserts that claim 30 is vague and unclear because it is unclear what step in the method of claim 31 included thawing BMSCs.

Applicants have amended claim 30 to recite "The method of Claim 31, further comprising: (f) thawing the cryopreserved transfected BMSCs." As step (e) of claim 30 is "storing the transfected BMSCs at about -80°C",

applicants submit that it is clear that step (f) of amended claim 30 (thawing the BMSCs) will follow step (e) of claim 31 (freezing the BMSCs). Accordingly, applicants respectfully request that the rejection of claim 30 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention be withdrawn.

**The 35 U.S.C. §§102 and 103 Rejections**

Claims 21, 22, 24 to 27, and 34 have been rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Greenberger et al. (EP 0381490). The Examiner asserts that although Greenberger et al. (EP 0381490) does not disclose a transfected BMSC which has been cryopreserved, the transfected BMSCs of Greenberger et al. (EP 0381490) are indistinguishable from the thawed BMSCs of Claims 21, 22, 24 to 27, and 34.

Claim 34 has been canceled.

Applicants have amended Claim 21 to be directed to BMSCs which have been cryopreserved according to a method of the present invention. Accordingly, the BMSCs of amended claim 21, which have been frozen, are readily distinguishable from the BMSCs of Greenberger et al. (EP 0381490), which have not been frozen. In view of this amendment, applicants respectfully request that the rejections of claims 21, 22, and 24 to 27 under 35 U.S.C. §102(b) as being anticipated by, or in

the alternative, under 35 U.S.C. §103(a) as being obvious over Greenberger et al.  
(EP 0381490) be withdrawn.

Claims 21, 23, 24 to 26, and 34 have been rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Lozier et al. (Hum. Gene Ther. 1994). The Examiner asserts that although Lozier et al. does not disclose a transfected BMSC which has been cryopreserved, the transfected BMSCs of Lozier et al. are indistinguishable from the thawed BMSCs of Claims 21, 23, 24 to 26, and 34.

Claim 34 has been canceled.

Applicants have amended Claim 21 to be directed to BMSCs which have been cryopreserved according to a method of the present invention. Accordingly, the BMSCs of amended claim 21, which have been frozen, are readily distinguishable from the BMSCs of Lozier et al., which have not been frozen. In view of this amendment, applicants respectfully request that the rejections of claims 21, 22, and 24 to 27 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Lozier et al. be withdrawn.

Claims 21, 27, and 28 have been rejected under 35 U.S.C. §103(a) as being obvious over Greenberger et al., in view of Newman et al. (U.S. 6,020,188).

Newman et al. has been cited for the teaching of transfection with cell adhesion molecules. Newman et al. does not provide any teaching to overcome the deficiencies of Greenberger et al. as discussed above. Accordingly, applicants respectfully request that the rejections of claims 21, 27 and 28 under 35 U.S.C. §103(a) as being obvious over Greenberger et al. in view of Newman et al. be withdrawn.

Claims 21, 22, 24 to 27, and 34 have been rejected under 35 U.S.C. §102(e) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354). The Examiner asserts that although Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354) does not disclose a transfected BMSC which has been cryopreserved, the transfected BMSCs of Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354) are indistinguishable from the thawed BMSCs of Claims 21, 22, 24 to 27, and 34.

Claim 34 has been canceled.

Applicants have amended Claim 21 to be directed to BMSCs which have been cryopreserved according to a method of the present invention. Accordingly, the BMSCs of amended claim 21, which have been frozen, are readily distinguishable from the BMSCs of Greenberger et al. (US 5,849,287 or US 5,993,801 or US

6,258,354), which have not been frozen using the method of the present invention.

In view of this amendment, applicants respectfully request that the rejections of claims 21, 22, and 24 to 27 under 35 U.S.C. §102(e) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354) be withdrawn.

Claims 21, 22, 24 to 27, and 34 have been rejected under 35 U.S.C. §102(f) because the applicants did not invent the claimed subject matter in view of Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354). As noted above, the BMSCs of amended claim 21, which have been frozen, are readily distinguishable from the BMSCs of Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354), which have not been frozen using the method of the present invention. In view of this amendment, applicants respectfully request that the rejections of claims 21, 22, and 24 to 27 under 35 U.S.C. §102(f) in view of Greenberger et al. (US 5,849,287 or US 5,993,801 or US 6,258,354) be withdrawn.

#### **The Obviousness-type Double Patenting Rejections**

Claims 21, 22, 24 to 27, and 34 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of US 5,849,287 or claims 1-19 of US 5,993,801 or claims 1-9 of US

6,258,354. The Examiner asserts that although US 5,849,287, US 5,993,801, and US 6,258,354 do not disclose a transfected BMSC which has been cryopreserved, the transfected BMSCs of claims 1-10 of US 5,849,287, claims 1-19 of US 5,993,801, and claims 1-9 of US 6,258,354 are indistinguishable from the thawed BMSCs of Claims 21, 22, 24 to 27, and 34.

Claim 34 has been canceled.

As noted above, the BMSCs of amended claim 21, which have been frozen, are readily distinguishable from the BMSCs of claims 1-10 of US 5,849,287, claims 1-19 of US 5,993,801, and claims 1-9 of US 6,258,354, which have not been frozen using the method of the present invention. In view of this amendment, applicants respectfully request that the rejections of claims 21, 22, and 24 to 27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of US 5,849,287 or claims 1-19 of US 5,993,801 or claims 1-9 of US 6,258,354 be withdrawn.

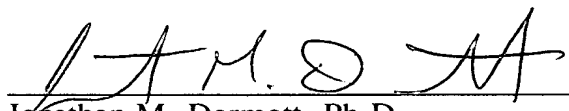
#### **The Objections to Claims 2 to 11 and 31 to 33**

Claim 31 has been objected to because the preamble of the claim is directed to preserving any cell type. Applicants have amended claim 31 to recite, "A method for preserving bone marrow stromal cells (BMSCs) comprising...". Accordingly, applicants respectfully request that the objection to claim 31 be withdrawn.

Claims 2 to 11, 32 and 33 have been objected to for being dependent upon an objected base claim (claim 31). In view of the amendment to claim 31 discussed above, applicants respectfully request that the objection to claims 2 to 11, 32 and 33 be withdrawn.

A favorable action on the merits is requested respectfully. A Petition for a one-month extension of time to respond to the Action, from November 18, 2004 to December 18, 2004, a Saturday, is enclosed.

Respectfully submitted,



Jonathan M. Dermott, Ph.D.  
Registration No. 48,608

SYNNESTVEDT & LECHNER LLP  
Suite 2600 Aramark Tower  
1101 Market Street  
Philadelphia, PA 19107  
(215) 923-4466 - telephone  
(215) 923-2189 - facsimile